

Aerotel Medical Systems (1998) Ltd.
Special 510(k)
MPM-Net

MAR 28 2003

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements Regulation par. 807.92, effective March 14, 1995.

1. Submitter

Name: Aerotel Medical Systems (1998) Ltd
Address: 5 Hazoref St., Holon 58856, Israel
Telephone Number: 972-3-5596111
Contact person: Dr. George Myers, 210-787- 1703
Date prepared: April 1, 2002

2. Device

Proprietary name: MPM-Net
Common Name: Home blood-pressure measurement device and trans-telephonic transmission system.
Classification Name: Monitor, Blood-Pressure, Amplifier and Associated Electronics

3. Predicate Devices

BP-Tel K983717, manufactured by Aerotel
TeleCliniQ Clinical Data Transmission System, K021447, manufactured by Aerotel

4. Description

The MPM-Net is an option for a modem/dialer system adapted for the purpose of following patients' blood pressures. It operates in conjunction with a cleared home-use blood pressure device. The system includes the computer program at a central station used for receiving data and preparing reports. The option allows reports to be retrieved over the internet.

5. Intended Use

The intended use of this device in conjunction with the devices previously cleared is to:

1. Provide means so that a patient can measure his/her blood pressure at home
2. Send the measurement in to central computer
3. Provide means so that a physician can monitor progress on the central computer.

6. Comparison

The MPM-Net is a modified version of the predicate device. It has basically the same electrical and mechanical characteristics, and the use of the two devices by the patient is equivalent. It permits the reports to be retrieved over the internet.

7. Performance Data

(1) Non-clinical tests

The modifications were validated by a validation test for the system.

(2) Clinical Tests

No clinical tests were performed.

8. Conclusion

The conclusion drawn from these tests is that the MPM-Net is equivalent in safety and efficacy to its predicate device.



MAR 28 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aerotel Medical Systems (1998) Ltd.
c/o Dr. George Myers
Medsys Inc.
Official Correspondent
377 Rt. 17
Hasbrouck Heights, NJ 07604

Re: K030825

Trade Name: MPM-Net
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: March 13, 2003
Received: March 14, 2003

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

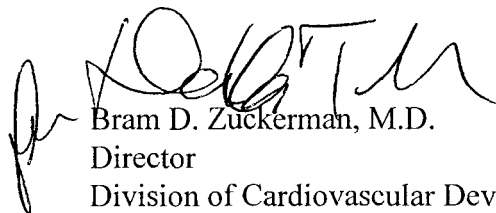
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the printed name and title.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

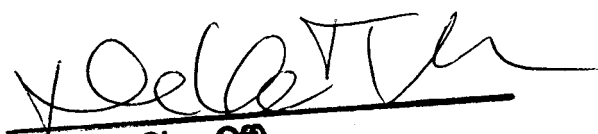
Enclosure

Page 1 of 1510(k) Number (if known): K030825**Indications for Use Form****Device Name: MPM-Net****Indications for Use:**

The Aerotel Medical Systems (1998) Ltd. MPM-Net system is intended to be used by patients to measure their blood pressure at home and transmit it to a central station by telephone. The system includes both the patient unit and a central computer program (to be used in a Personal Computer) which receives the blood pressure data, stores it in a patient's record, and prepares reports and charts showing the history of the systolic, diastolic pressures and the heart rate. The system is not intended for patients with defibrillators.

**(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER
PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030825**Prescription Use Only**